

“[c]ontinuity of the sheath is interrupted by longitudinal grooves 18, which serve to accommodate, guide, and protect the tips of the cutting edges. The protective sheath prevents vessel injuries during delivery and holds the cutting edges in proper position prior to balloon inflation”
(col. 5, lines 20-29, emphasis added).

In reference to Fig. 13, Barath further states

The grooves 18 of the protective sheath 17 open up allowing the cutting edges 6 to penetrate into the vessel wall 7,8 producing cuts with sharp margins 11. After deflation, the cutting edges retract behind the protective sheath
(col. 5, lines 30-36, emphasis added).

For reference portions of Figs. 12 and 13 have been enlarged, annotated and provided below. When the balloon is in a deflated state, as shown in Fig. 12, the longitudinal groove 18 is very small, i.e. the distance separating the two edges of the sheath 17 is small. In contrast, when the balloon 2 is inflated, the longitudinal groove “opens up” thereby increasing the distance separating the two edges of the sheath 17. Thus, *inflation of the balloon* causes the size of the longitudinal groove 18 to change from a narrow groove to a wide groove. When the size of each longitudinal groove 18 gets larger/wider, each cutting edge 6 is exposed so that it can “penetrate into the vessel wall 7,8 producing cuts with sharp margins 11” (col. 5, lines 30-34).

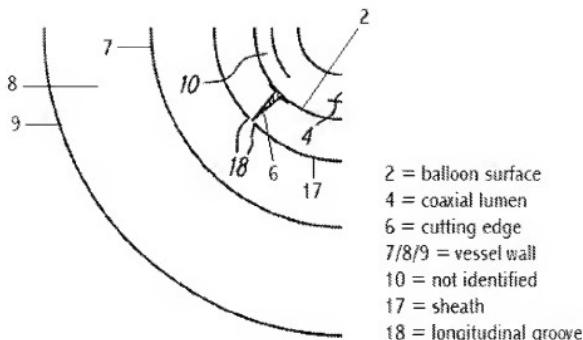


Fig. 12 of Barath Annotated
balloon is deflated and longitudinal
groove 18 is small/narrow

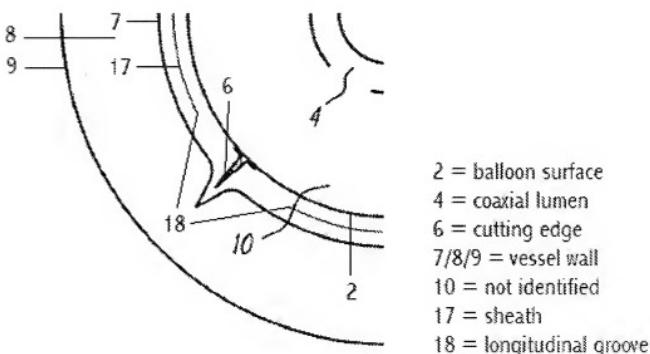


Fig. 13 of Barath Annotated
balloon is inflated and longitudinal
groove 18 is large/wide

Note that the distance separating the balloon surface 2 and the sheath 17 decreases when the balloon 2 is in an inflated state as compared to a deflated state (compare Fig. 12 to Fig. 13). In addition, the position of the sheath 17 relative to the length of the cutting edge 6 also changes depending on whether the balloon 2 is inflated or deflated. Thus, when the balloon 2 is deflated, as shown in Fig. 12, the sheath 17 is about even with the tip of the cutting edge 6, while when the balloon 2 is inflated, the sheath 17 is positioned about halfway between the tip of the cutting edge 6 and the base of the cutting edge 6.

Thus, in Barath, the inflation of the balloon 2, not radial compression of the balloon 2 against the vessel wall, causes the longitudinal grooves 18 in the sheath 17 to widen and retreat from the tip of the cutting edge 6, thereby exposing the cutting edge 6. Contrary to the assertion in the Office Action, Barath does not state that compression of the balloon against the vessel wall exposes the cutting edge. Therefore Barath does not teach or suggest “a radially compressible sheath ... being positioned for *radial compression between said tissue and said balloon to expose said surface feature for tissue incision* when said balloon is inflated into the second configuration,” as recited in the instant claims.

For at least this reason, Applicants request withdrawal of the rejection and assert that claims 1, 2, 8, and 10 are in condition for allowance.

35 USC 103 – Barath

In the Final Office Action, claims 11-14 were rejected under 35 USC 103(a) as being unpatentable over Barath (5,616,149). As discussed above, Barath does not teach or suggest all the elements of independent claim 1, from which claims 11-14 depend. For at least this reason, Applicants request withdrawal of the rejection and assert that claims 11-14 are in condition for allowance.

35 USC 103 – Barath in view of Vigil

In the Final Office Action, claims 3-4 were rejected under 35 USC 103(a) as being unpatentable over Barath (5,616,149) in view of Vigil (5,320,634). As discussed above, Barath does not teach or suggest all the elements of independent claim 1, from which claims 3-4

depend. The addition of Vigil, which is asserted to teach an incising element being partially encapsulated in said mounting pad, does nothing to address the failure of Barath to teach or suggest all the elements of the instant claims. For at least this reason, Applicants request withdrawal of the rejection and assert that claims 3-4 are in condition for allowance.

35 USC 103 – Barath in view of Shiber

In the Final Office Action, claim 5 was rejected under 35 USC 103(a) as being unpatentable over Barath (5,616,149) in view of Shiber (6,730,105). Claim 5 depends upon independent claim 1.

As discussed above, Barath does not teach or suggest all the elements of independent claim 1, from which claim 5 depends. The addition of Shiber, which is asserted to teach a sheath having a pair of sheath members, does nothing to address the failure of Barath to teach or suggest all the elements of the instant claim.

In the Response to Arguments, the Final Office Action asserted that “the halves of 53 or 55 seen in Figure 18 read on a pair of sheath members of either side of the incising element being mounted on a balloon 77.”

Applicants note that in the 35 USC 103(a) rejection, the sheath is asserted to be the “upper surface of element 15” and that the sheath has “a pair of sheath members (on either side of cutting blade 54) being positioned on said balloon to interspose (*sic*) said incising element 54 between said sheath members.”

Applicants disagree that shield 77 is a balloon as asserted in the Final Office Action. Shiber teaches that “the guidewire 61 can be disposed in a shield 77 that isolates the guidewire from the fluid that flows in conduit 69, as shown in FIG. 13 and in the fourth and fifth embodiments shown in FIGS. 14 to 21” (col. 5, lines 33-47). As recited in independent claim 1, the elongated balloon is inflatable. Shiber does not teach or suggest that the shield 77 is inflatable. This is contrary to independent claim 1

Even if the shield 77 is a balloon as recited in instant claim 1, neither the halves 53 or 55, nor the parting edge are mounted on the shield, aka “balloon,” contrary to independent claim 1 which recites “an elongated incising element **mounted on said balloon** ... and a radially compressible sheath **mounted on said balloon**” (emphasis added). Shiber states the embodiment

shown in Fig. 18 “utilizes ridges 95 comprising an arch 53 that is *bonded to the expandable tube 15*” and that the “mid section of the arch 55 is thicker ... to better support the parting edge 54” (col. 6, lines 8-12 and 23-24, emphasis added). Thus, the halves 53/55 are “bonded to the expandable tube 15,” not “balloon 77” and the “parting edge 54 is attached to a mid section of the ridge,” not “balloon 77” contrary to independent claim 1 (col. 6, lines 11-13). This is shown in Fig. 20 of Shiber, provided below, which shows the expandable tube 15 in an inflated state:

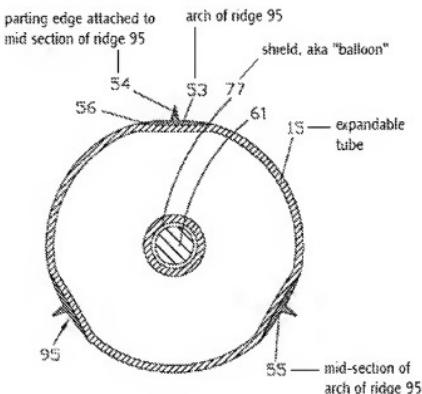


FIG. 20

Additionally, even if the halves 53/55 are a pair of sheath members, they are not “positioned for radial compression between said tissue and said balloon to expose said surface feature for tissue incision when the balloon is inflated into the second configuration” as recited in independent claim 1. Shiber states that “[a]s the expandable tube is inflated and expanded the parting edge moves out of the arch (note FIG. 20) to part the surrounding obstruction.” Thus, *inflation of the expandable tube exposes the parting edge, not* compression of the halves 53/55 between the shield, aka “balloon” and the tissue.

For at least these reasons, Shiber does not teach or suggest a sheath having a pair of sheath members as recited in instant claim 5. Thus, the combination of Barath and Shiber does not teach or suggest all the elements of instant claim 5. Applicants request withdrawal of

the rejection and assert that claim 5 is in condition for allowance.

35 USC 103 – Barath in view of Shiber and Vigil

In the Final Office Action, claim 9 was rejected under 35 USC 103(a) as being unpatentable over Barath (5,616,149) in view of Shiber (6,730,105) and Vigil (5,320,634).

As discussed above, Barath does not teach or suggest all the elements of independent claim 1, from which claim 9 depends. The Final Office Action asserts that “Barath does not expressly [dis]close the sheath member having an azimuthal width” and that “Shiber teaches a sheath member (upper surface of element 15) having an azimuthal width w, and wherein said blade 54 has an azimuthal width, W, where said blade extends from said mounting pad, with $w > 2W$ (Figure 18; col. 6, lines 8-21).” Applicants note neither the azimuthal width of element 15 nor the azimuthal width of blade 54 is discussed in col. 6, lines 8-21 of Shiber, provided below for reference:

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creates a series of short cuts in the obstruction material along which the obstructing material preferentially parts. Upon deflation the flexible arch 41 urges the expandable tube to return to its clover leaf shape. While the ridge 94 is shown with a parting edge at each of its ends, optionally, additional ridges can be attached to the arch or a single ridge can be attached to an arch as illustrated in the next embodiment. FIGS. 18 to 21 show a fifth embodiment with a clover leaf shaped expandable tube 15 with pleats 51 that increase the expanded tube's diameter (note FIG. 20). This embodiment utilizes ridges 95 comprising an arch 53 that is bonded to the expandable tube 15. A parting edge 54 is attached to a mid section of the ridge so that when the expandable tube and the ridge are in their relaxed position the parting edge is retracted inwardly in the arch (note FIG. 18) This shields the un-inflated tube 15 and blood vessel from the parting edge and reduces the likelihood of the expandable tube or vascularise being damaged by the parting edge during introduction and advancement or withdrawal of the catheter in the vasculature. As the expandable tube is inflated and expanded the parting edge moves out of the arch (note FIG. 20) to part the surrounding obstruction.

The addition of Vigil, which is asserted to teach an incising element 31 being partially encapsulated in said mounting pad 32, does nothing to address the failure of Barath and Shiber to teach or suggest all the elements of instant claim 9. Therefore the combination of Barath, Shiber and Vigil do not render instant claim 9 obvious. Applicants request withdrawal

of the rejection and assert that claim 9 is in condition for allowance.

Allowable Subject Matter

In the Final Office Action, claims 6, 7, and 15-24 were allowed.

As discussed above, the combination of Barath and Shiber does not render claim 5, from which claims 6 and 7 depend, obvious. Because claim 5 is patentable, Applicants assert that claims 6 and 7 are patentable in their current form.

Applicants acknowledge the finding of allowable subject matter in instant claims 15-24.

Conclusion

Based on at least the above, Applicants respectfully submit that this application is in condition for allowance. Favorable consideration and prompt allowance of claims 1-24 is requested.

Should the Examiner believe that anything further would be desirable in order to place this application in better condition for allowance, the Examiner is invited to contact Applicants' undersigned representative at the telephone number listed below.

Respectfully submitted,

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